

### **REMARKS/ARGUMENTS**

Reconsideration and continued examination of the above-identified application are respectfully requested.

In the present amendment, claims 1-4, 44, 45, and 117 have been amended. Claims 1-4 have been amended to recite the transitional phrase "consisting of." Claims 44 and 45 have been amended to correct a typographical error, wherein the word "peptide" has been added after "at least one." Claim 117 has been amended to simplify the claim. Accordingly, no questions of new matter should arise and entry of this amendment is respectfully requested.

### **Specification**

At page 2 of the Office Action, the Examiner requested that Applicants amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification. The Examiner also objected to the identification of the sequence DYLRVS, which the Examiner argues is a subsequence of SEQ ID NO: 2, and should be identified as such.

In response, the specification has been amended to list the appropriate SEQ ID NOS for sequences disclosed in the present application at pages 13, 14, 36, and 37.

### **Objection to the Abstract**

In the Office Action at page 3, the Examiner objects to the abstract and argues that the abstract does not adequately describe the claimed invention. The Examiner requests clarity as to whether it is an incorrect translation of the abstract from the Japanese parent application. For the following reasons, this objection is respectfully traversed.

The objections raised by the Examiner are translation-related and the Abstract has been

amended by way of this amendment. Full support for this amendment can be found throughout the present application. Essentially, editorial changes have been made to the Abstract to make it clearer.

With regard to the Examiner noting that there are two sets of the specification filed on the same day, the applicants do not fully understand this comment. When the present application was filed on February 1, 2002, one application having 63 pages and 15 sheets of drawings was submitted. The Japanese version of the PCT application was further submitted. Clarification is respectfully requested.

Accordingly, the Examiner is respectfully requested to withdrawn this objection.

**Rejection of Claims 3-4 under 35 U.S.C. §112, first paragraph -- Written Description Requirement**

At pages 3-4 of the Office Action, the Examiner rejects claims 3 and 4 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter that is not described in the specification in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

More particularly, the Examiner asserts that the term "inducer" is not defined in the specification and that the claimed inducers cover a broad category of inducers that comprise peptides and non-peptides. For the following reasons, this rejection is respectfully traversed.

The applicants believe that claims 3 and 4 are adequately disclosed in the present application, including the examples. To assist the Examiner and to make the claims more clear, claims 3 and 4 have been amended to recite that the "inducer" is an inducer of cytotoxic T lymphocytes wherein the activator consists essentially of a peptide of claim 1. Claim 4 has been

amended in a similar fashion. These claims are clearly defined and described in the present application and would not cover "a broad category of inducers" that comprise peptides and non-peptides that are not disclosed in the specification.

For these reasons, this rejection should be withdrawn.

**Rejection of Claims 7, 8, 44, and 45 under 35 U.S.C. §112, first paragraph -- Written Description Requirement**

At pages 4-6 of the Office Action, the Examiner rejects claims 7, 8, 44, and 45 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter that is not described in the specification in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. For the following reasons, this rejection is respectfully traversed.

The present application, for instance, beginning at page 22, clearly describes pharmaceutical compositions and vaccines. The present application clearly shows the ability of the present application to induce HLA-A 24-restricted and tumor-specific cytotoxic T lymphocytes. The fact that testing is shown in the present application from cells obtained from cancer patients, certainly, is evidence to show that the present application would serve as a suitable pharmaceutical composition and vaccine.

In addition, clinical results for the present application are published in CLIN. CANCER RES. 2005, Vol. 11 (16), August 15, 2005, pp. 5900-5911 (a copy is attached). These results clearly show the superior clinical effect of the present application. This evidence confirms the disclosure set forth in the present application.

For these reasons, this rejection should be withdrawn.

**Rejection of Claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §112, first paragraph -- Written Description Requirement**

At pages 6-7 of the Office Action, the Examiner rejects claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims contain subject matter that is not described in the specification in a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

As shown at the top of page 7 of the Office Action, it appears that the Examiner is rejecting the claims partially in view of the fact that "having" is being used. In view of this interpretation of the claims taken by the Examiner, the Examiner then takes the position that the unrecited components that can be possibly present due to the scope of the claim would create a lack of written description problem. For the following reasons, this rejection is respectfully traversed.

Claims 1 and 2 now recite that the peptide consists of the amino acid sequence set forth in claims 1 and 2. Clearly, these peptides are described and enabled in the present application and, further, claims 7, 8, 44, 45, and 117 would further be enabled for the same reasons and in view of the evidence provided in the present application, for instance, beginning at page 22 of the present application and elsewhere. Clearly, the present specification provides an adequate description of the peptides, pharmaceutical compositions, and vaccines of the present application.

For these reasons, this rejection should be withdrawn.

**Rejection of claims 1-4, 7, 8, 44, 45, and 117 under 37 U.S.C. §112, first paragraph -- Enablement**

At page 8 of the Office Action, the Examiner rejects claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §112, first paragraph, for enablement reasons. The Examiner asserts that the specification does not disclose how to make and/or use the present invention with respect to the claimed inducer of CTL recited in claims 3 and 4. The Examiner further asserts that the specification does not disclose how to make and/or use the present invention with respect to the claimed pharmaceutical composition recited in claims 44 and 45. In addition, the Examiner asserts that the specification does not disclose how to make and/or use the present invention with respect to the claimed peptide "having" an amino acid sequence as recited in the claims. For the following reasons, this rejection is respectfully traversed.

As indicated above, claims 1 and 2 have been amended to recite that the peptide consists of the sequences set forth in claim 1 or claim 2. Further, claims 3 and 4 have been amended to recite an inducer of cytotoxic T lymphocytes wherein the inducer consists essentially of the peptide of claim 1 or the peptide of claim 2. In view of these amendments, as well as the disclosure set forth in the present application, for instance, beginning at page 22 and continuing with the examples, there is a clear teaching to permit one skilled in the art to make and use the claimed invention as recited in the claims.

For these reasons, this rejection should be withdrawn.

**Rejection of claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §112, second paragraph -- Indefiniteness**

At pages 12-13 of the Office Action, the Examiner rejects claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention.

The Examiner argues that claims 1 and 2 are indefinite in the recitation of "having an amino acid sequence of SEQ ID No." For the following reasons, this rejection is respectfully traversed.

As described above, claims 1 and 2 now recite "consisting of" and, therefore, these peptides are clearly described in the present application and would be definite to one skilled in the art.

With respect to the Examiner's comments regarding claims 3 and 4 being indefinite, as stated above, claims 3 and 4 recite an inducer of cytotoxic T lymphocytes consisting essentially of the peptide of claim 1 or claim 2, and this is clearly described in the present application. For instance, see pages 11-15 of the present application.

With respect to claims 44 and 45, the term "peptide" has been added to the claims to make them clearer.

With respect to claim 117, claim 117 has been amended to delete the language objected to, and claim 117 should be even more clearer in view of this amendment.

For these reasons, the rejection should be withdrawn.

**Rejection of claims 1 and 2 under 35 U.S.C. §102(b) -- Voronova et al.**

At page 13 of the Office Action, the Examiner rejects claims 1 and 2 under 35 U.S.C. §102(b) as being anticipated by Voronova et al. (NATURE, 319, 682-685, 1986). For the following reasons, this rejection is respectfully traversed.

Claims 1 and 2 have replaced the term "comprising" with "consisting of," and clearly, Voronova et al. does not teach these specific sequences.

Accordingly this rejection should be withdrawn.



**Rejection of claims 1-4 under 35 U.S.C. §102(b) -- Harashima et al.**

At page 13 of the Office Action, the Examiner rejects claims 1-4 under 35 U.S.C. §102(b) as being anticipated by Harashima et al. (EUR. J. IMMUNOL. 31: 323-332, 2001, date of public availability 1/22/01.) For the following reasons, this rejection is respectfully traversed.

Attached to this response is a certified English translation of the International Application No. PCT/JP00/05220, from which the present application claims priority. As can be seen, all claims as pending are fully supported in the original PCT application, which has a filing date of August 3, 2000. Therefore, Harashima et al. would not be prior art to the claimed invention.

For this reason, the rejection should be withdrawn.

**Rejection of claims 1-4 under 35 U.S.C. §102(b) -- WO 97/22255 A1**

At page 14 of the Office Action, the Examiner rejects claims 1-4, under 35 U.S.C. §102(b), as being anticipated by WO 97/22255 A1. For the following reasons, this rejection is respectfully traversed.

Again, like Voronova et al., WO 97/22255 does not teach the claimed sequences specifically recited and, therefore, this rejection should be withdrawn.

**Rejection of claims 1-4 under 35 U.S.C. §102(e) -- Hooegeveen et al.**

At page 14 of the Office Action, the Examiner rejects claims 1-4 under 35 U.S.C. §102(e), as being anticipated by Hooegeveen et al. (U.S. Patent No. 6,635,623 B1). The Examiner alleges that U.S. Patent No. 6,635,623 B1 discloses a peptide comprising SEQ ID NO: 1 and 2 of the instant claims (SEQ ID NO: 74 of the reference). For the following reasons, this rejection is

respectfully traversed.

Again, like Voronova et al., Hoogeveen et al. does not teach the claimed sequences specifically and, therefore, this rejection should be withdrawn.

**Rejection of claims 1-4, 7, 8, 44, and 45 under 35 U.S.C. §102(e) -- Rudd et al.**

At page 14 of the Office Action, the Examiner rejects claims 1-4, 7, 8, 44, and 45 under 35 U.S.C. §102(e), as being anticipated by Rudd et al. (U.S. Patent No. 5,432,076). The Examiner alleges that U.S. Patent No. 5,432,076 discloses a peptide comprising SEQ ID NO: 1 and 2 of the instant claims (the sequence appearing at column 5, lines 23-27 of the reference). The Examiner asserts that U.S. Patent No. 5,432,076 discloses that the peptide was used to raise an antiserum in rabbits, i.e., the composition is a pharmaceutical composition. For the following reasons, this rejection is respectfully traversed.

Again, like Voronova et al., Rudd et al. does not teach the claimed sequences specifically and, therefore, this rejection should be withdrawn.

**Rejection of Claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §103(a) -- Harashima et al., in view of Nag et al. and De Bruijn et al.**

At pages 15-16 of the Office Action, the Examiner rejects claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §103(a), as being unpatentable over Harashima et al. in view of Nag et al. (U.S. Patent No. 5,734,023) and De Bruijn et al. (EUR. J. IMMUNOL. 1991, 21: 2963-2790). For the following reasons, this rejection is respectfully traversed.

As indicated, attached to this response is a certified English translation of the International Application No. PCT/JP00/05220, from which the present application claims priority. As can be seen, all claims as pending are fully supported in the original PCT application, which has a filing



U.S. Patent Application No. 10/062,257  
Amendment dated November 17, 2006  
Reply to Office Action of August 18, 2006

date of August 3, 2000. Therefore, Harashima et al. would not be prior art to the claimed invention.

For this reason, the rejection should be withdrawn.

**Rejection of claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §103(a) -- Rudd et al. in view of Nag et al.**

At pages 17-18 of the Office Action, the Examiner rejects claims 1-4, 7, 8, 44, 45, and 117 under 35 U.S.C. §103(a) as being unpatentable over Rudd et al. (U.S. Patent No. 5,432,076) in view of Nag et al. (U.S. Patent No. 5,734,023).

Again, like Voronova et al., Rudd et al. and Nag et al. do not teach or suggest the claimed sequences specifically and, therefore, this rejection should be withdrawn.

**Objection to Claims 1 and 44**

At page 18 of the Office Action, the Examiner objects to claims 1 and 44.

In response, claims 1 and 2 have been amended to remove the phrase "in the sequence listing." With respect to claim 44, claim 44 does have a period at the end of the claim and, perhaps, this just may not be seen in the Examiner's copy. Accordingly, no amendments are needed to claim 44.

**Information Disclosure Statement -- Failure to Comply with 37 CFR 1.98(a)(1)**

At page 18 of the Office Action, the Examiner states that the Information Disclosure Statement (IDS) filed 6/14/02 fails to comply with 37 CFR 1.98(a)(1). Specifically, the Examiner asserted that the Form 1449 filed 6/14/02 did not include any list of patents, or patent application publications for consideration by the Office.

With respect to this objection, the Examiner's objection is not understood and appears to be

U.S. Patent Application No. 10/062,257  
Amendment dated November 17, 2006  
Reply to Office Action of August 18, 2006

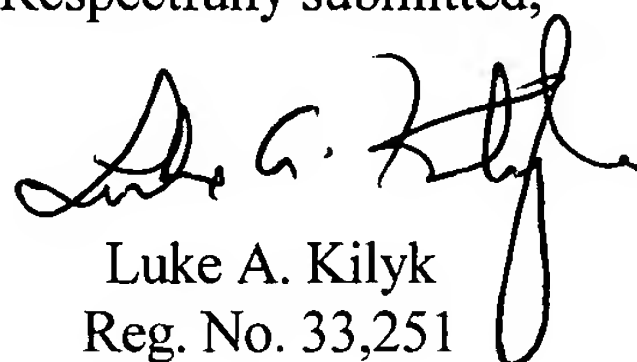
incorrect. The Information Disclosure Statement dated June 10, 2002 was correct and did list the International Preliminary Examination Report at the bottom. The Examiner may have not realized that this was listed in the Form PTO-1449, and the Examiner is requested to make proper consideration of the International Preliminary Examination Report, and to initial the Form PTO-1449.

### **CONCLUSION**

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

  
Luke A. Kilyk  
Reg. No. 33,251

Atty. Docket No. 3190-014  
KILYK & BOWERSOX, P.L.L.C.  
400 Holiday Court, Suite 102  
Warrenton, VA 20186  
Tel.: (540) 428-1701  
Fax: (540) 428-1720

Attachments: CLIN. CANCER RES. 2005, Vol. 11 (16), August 15, 2005, pp. 5900-5911  
Certified English translation of the International Application No. PCT/JP00/05220